

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

MDL Docket No. 2738

This Document Relates To All Cases

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT,
LLC'S MEMORANDUM OF LAW IN OPPOSITION TO THE
PLAINTIFFS' STEERING COMMITTEE'S MOTION TO EXCLUDE THE
OPINIONS OF DRS. JUAN FELIX AND TERI LONGACRE**

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INTRODUCTION

Drs. Juan Felix and Teri Longacre, two internationally recognized gynecologic pathologists, seek to testify that the pathological evidence does not support plaintiffs' contention that talcum powder use caused each bellwether plaintiff's ovarian cancer. Plaintiffs do not seek to exclude most of their opinions. Rather, they only seek to bar Drs. Felix and Longacre from testifying that talc-like substances allegedly found by plaintiffs' expert Dr. Godleski on certain plaintiffs' tissue samples may have resulted from contamination. Plaintiffs suggest that these opinions are speculative and that the experts are not qualified to offer them. Neither argument has any merit.

BACKGROUND

Dr. Felix is "an internationally recognized expert in the field of diagnostic gynecologic pathology and [is] frequently consulted on challenging diagnostic cases by pathologists throughout the United States and internationally."¹ Similarly, Dr. Longacre is a "board-certified diagnostic surgical pathologist at Stanford Medicine with subspecialty expertise in gynecologic pathology."² She

¹ (Rep. of Juan Felix Re: Hilary Converse ("Felix *Converse* Rep.") at 2, May 28, 2024 (Ex. 1 to Decl. of Jessica Davidson ("Davidson Decl.")).)

² (Rep. of Teri Longacre re: Tamara Newsome ("Longacre *Newsome* Rep.") at 2, May 28, 2024 (Ex. 2 to Davidson Decl.).)

has “internationally recognized expertise in benign and cancerous conditions of the female reproductive system.”³

In their reports, Drs. Felix and Longacre respond, among other things, to plaintiffs’ expert Dr. Godleski, a (non-gynecologic) pathologist who claims to have identified particles consistent with talc and/or asbestos in tissue samples taken from five of the bellwether plaintiffs’ ovaries, fallopian tubes, and pelvic tissues.⁴ Dr. Godleski asserts that the alleged presence of these particles is “contributory evidence for a causal link” between each plaintiff’s alleged talc exposure and her development of ovarian cancer.⁵

³ (*Id.*)

⁴ (*See, e.g.,* Godleski Newsome Rep. at 7; *see also* Rep. of John Godleski Re: Anna Gallardo (“Godleski Gallardo Rep.”), July 21, 2021 (Ex. 3 to Davidson Decl.); Rep. of John Godleski Re: Hilary Converse (“Godleski Converse Rep.”), July 12, 2021 (Ex. 4 to Davidson Decl.); Rep. of John Godleski Re: Tamara Newsome (“Godleski Newsome Rep.”), June 24, 2021 (Ex. 5 to Davidson Decl.); Rep. of John Godleski Re: Carter Judkins (“Godleski Judkins Rep.”), June 18, 2021 (Ex. 6 to Davidson Decl.).) Dr. Felix’s opinions respond to Dr. Godleski’s opinions with respect to plaintiffs Converse, Judkins, and Gallardo, whereas Dr. Longacre’s opinions respond to Dr. Godleski’s opinions with respect to Ms. Newsome. (*See* Felix Converse Rep.; Rep. of Juan Felix Re: Carter Judkins (“Felix Judkins Rep.”), May 28, 2024 (Ex. 7 to Davidson Decl.); Rep. of Juan Felix Re: Anna Gallardo (“Felix Gallardo Rep.”), May 28, 2024 (Ex. 8 to Davidson Decl.); Longacre Newsome Rep.)

⁵ (*Id.*) Defendants have moved to exclude Dr. Godleski’s opinions to the extent they assert or suggest that the bellwether plaintiffs’ particular cancers were caused by exposure to talc. (*See* Defs.’ Mem. of Law in Supp. of Mot. to Exclude Ops. of Dr. John Godleski (ECF No. 33004-2).)

Dr. Felix explains that there was no foreign body reaction associated with the particles Dr. Godleski identified in plaintiffs' tissue, meaning that the particles would not have been present in the plaintiffs' living tissue.⁶ Dr. Felix explains, based on six cited medical texts, that "[it] is well known that talc, like virtually any foreign body, will cause a foreign body granulomatous reaction when introduced into vital (living) tissue."⁷ According to Dr. Felix, the slides of the ovary tissue that Dr. Godleski examined "reveal[] a complete absence of this characteristic histologic reaction to talc (or other foreign material)."⁸ In other words, none of the particles Dr. Godleski found were in macrophages or otherwise associated with a foreign body reaction.⁹ "Similarly, careful histologic examination revealed no evidence of asbestos exposure (i.e., ferruginous bodies or foreign body fibers consistent with asbestos)."¹⁰

Particularly in light of this finding, Dr. Felix notes that one must consider the possibility of contamination. In support of that opinion, Dr. Felix cites scientific literature explaining that "[n]either the operating room nor the histology laboratory are particle-free environments, and it is virtually impossible to prevent

⁶ (Felix *Converse* Rep. at 12.)

⁷ (*Id.* at 9.)

⁸ (*Id.*)

⁹ (*Id.* at 12.)

¹⁰ (*Id.* at 9.)

ubiquitous microscopic particulates from coming into contact with the lab instruments, containers, surfaces, reagents, and paraffin involved in the processing of surgical tissue specimens into pathology blocks and slides.”¹¹ Dr. Felix testified similarly at his deposition, noting that in his experience, contaminant talc particles are generally present on every histological slide because talc is ubiquitous in labs.¹² Further, based on his substantial experience, Dr. Felix explained that the processes used in the operating room and in preparing tissue for a pathologist’s examination are not designed to prevent particles of the size identified by Dr. Godleski from getting into the excised tissue.¹³ This is because the presence of such particles will not interfere with the pathologist’s examination and eventual diagnosis in most cases, and “measures to prevent introduction of these sort of ubiquitous microscopic contaminants would be prohibitively expensive while altogether unnecessary.”¹⁴ Thus, as Dr. Felix explains, pathologists understand that the “vast majority of tissue slides will have microscopic particulate matter” and that “[i]n the absence of an associated foreign body reaction, including the presence of foreign body giant cells and/or particle-laden macrophages . . . these particles are widely

¹¹ (*Id.* at 9-10 (citing McDonald 2019).)

¹² (Dep. of Juan Felix (“Felix Dep.”) 148:12-149:6, June 22, 2024 (Pls.’ Br. Ex. 2).)

¹³ (Felix *Converse* Rep. at 12.)

¹⁴ (*Id.*)

agreed by pathologists to be simple particulate contaminants introduced to the tissue at the time of surgical removal and/or tissue processing for histologic examination.”¹⁵

Notably, Dr. Godleski himself acknowledged that contaminants may have been present at the medical facilities that handled the plaintiffs’ tissues, including his lab, and that the tissue may have been contaminated on its surface, at a minimum.¹⁶ Dr. Godleski also explained that talc is a possible lab contaminant due to its presence on the gloves used in pathology departments, noting that “for many years, almost every pathology department just used boxes of 100 gloves that had a lot of particles on them and a lot of talc so that, if you sometimes look carefully at a block or a slide, you can see that contamination around the outside.”¹⁷

Further, while Dr. Godleski asserts that he took steps to mitigate the potential for contamination, Dr. Felix explains that these efforts were insufficient to reliably confirm that any particles identified were not the result of lab

¹⁵ (*Id.* at 9; *see also* Felix Dep. 192:20-193:19.)

¹⁶ (*See, e.g.*, Godleski *Converse* Rep. at 4; Godleski *Newsome* Rep. at 3; *see also* Dep. of John Godleski (“3/28/24 Godleski Dep.”) 170:10-19, Mar. 28, 2024 (Ex. 9 to Davidson Decl.) (“[W]e don’t analyze any particles that we find on the surface of the tissue because, even though it’s just the edge of the surface, it very -- has a definite chance of getting there by contamination in the laboratory. So we don’t analyze that.”).)

¹⁷ (Dep. of John Godleski (“3/29/24 Godleski Dep.”) 91:12-92:2, Mar. 29, 2024 (Ex. 10 to Davidson Decl.).)

contamination.¹⁸ For example, as noted by Dr. Felix, Dr. Godleski’s claim that he “‘removes’ contaminants from the tissue blocks by removing 50 microns of the block surface before SEM analysis ignores the fact that tissue specimens processed for histology are exposed to a number of organic compounds that permeate the tissue at the cellular level,” which allows any accompanying particulate matter to penetrate through and around cell membranes and to become embedded throughout the tissue and not just on the surface of the block.¹⁹

Dr. Longacre offers similar criticisms of Dr. Godleski’s opinions, explaining that:

At a minimum, a histologic response (e.g., foreign body reaction) in association with the presence of the . . . particles or the presence of particulate material within macrophages with clear displacement of the macrophage cytoplasm should be present to confirm actual exposure and to exclude artifact (e.g., Clement 2019; Reichert 2012; Perou 1973). In [the] absence of this response, it is more likely than not that the particles are processing contaminants or “innocent bystanders.”²⁰

In addition, Dr. Longacre notes that “many of the aggregates of birefringent material depicted by Plaintiff’s expert are sufficiently large that they would not be present in vivo without an associated foreign body response,” and “[i]n the absence

¹⁸ (See, e.g., Felix *Converse* Rep. at 12.)

¹⁹ (*Id.*)

²⁰ (Longacre *Newsome* Rep. at 14.) Dr. Longacre notes that she also saw “no evidence of ferruginous bodies in the available tissue to support exposure” to asbestos. (*Id.* at 15 n.1.)

of this expected response, one can only reliably conclude that this material is contaminate introduced during or after surgery.”²¹

As to the potential for contamination and Dr. Godleski’s purported efforts to mitigate the contamination, Dr. Longacre explains that Dr. Godleski “fail[ed] to recognize that laboratory processing of tissue specimens for histology can . . . introduce contaminants . . . deep within tissue,” and thus “did not control for the tissue processing following surgery.”²²

In short, Drs. Felix and Longacre opine that Dr. Godleski ignores scientific evidence suggesting that the particles he found were not present in live tissue and likely resulted from environmental contamination.

ARGUMENT

The standard for the admission of defense expert testimony pursuant to Rule 702 is set forth in defendants’ opposition to plaintiffs’ motions to exclude Drs. Permuth, DiFeo, and Boyd, which is filed herewith and incorporated herein. Drs. Felix and Longacre’s opinions responding to Dr. Godleski are admissible under this standard.

²¹ (*Id.* at 13, 15; *see also* Dep. of Teri Longacre 109:18-25, June 10, 2024 (Ex. 11 to Davidson Decl.).)

²² (*See, e.g.,* Longacre Newsome Rep. at 15-16.)

I. THE CRITICISMS OF DR. GODLESKI OFFERED BY DRs. FELIX AND LONGACRE ARE SUPPORTED BY RELIABLE SCIENCE.

Plaintiffs argue that Drs. Felix and Longacre’s opinions should be partially excluded because they allegedly cannot “establish within a reasonable degree of medical certainty” that contamination occurred, or that any particles purportedly identified in the plaintiffs’ tissue samples were not the cause of their cancers.²³ Plaintiffs also argue that Drs. Felix and Longacre “offer no methodology and no reliable scientific support for their opinions that” the particles Dr. Godleski purportedly found in the tissue samples at issue “are postmortem lab contaminants.”²⁴ These arguments misunderstand both the law and the experts’ opinions.

First, the law is clear that it is “entirely appropriate” for defense experts to offer what are, “essentially, critiques of [p]laintiffs’ experts’ evidence, methodologies, and conclusions.” *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018); *In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prods. Liab. Litig.*, 424 F. Supp. 3d 781, 799 (N.D. Cal. 2020) (denying motion to exclude defense experts in toxic tort case; “Defendants’ witnesses are primarily offered to explain what they believe are the flaws in the

²³ (Pls.’ Br. at 8.)

²⁴ (*Id.* at 4.)

analyses of plaintiffs' witnesses, and there is no basis to contend they lack the expertise or have applied flawed methodology in doing so.""). Defendants are not required to "'disprove' causation" and "must only produce 'credible evidence which tends to discredit or rebut the plaintiff's evidence' so as to 'convince the trier of fact that the alleged negligence was not the legal cause of the injury.'"

Shadrick v. S. Health Partners, Inc., No. 11-00033, 2016 WL 4555611, at *10 (W.D. Ky. Aug. 31, 2016) (citations omitted).

Dr. Godleski seeks to testify that the mere identification of particles that are consistent with talc and asbestos in lab samples of some of the plaintiffs' tissues suggests that those plaintiffs' cancers were caused by talc use.²⁵ Drs. Felix and Longacre are permitted to poke holes in that opinion by explaining that the relevant pathology does not demonstrate a foreign body reaction around the particles and is therefore inconsistent with plaintiffs' theory of causation. They are also entitled to testify that Dr. Godleski ignored the alternative explanation that the identified particles are the result of environmental contamination. Contrary to plaintiffs' assertion, Drs. Felix and Longacre do not need to "prove . . . with certainty or probability" that such contamination occurred, or that any particles purportedly identified in the plaintiffs' tissue samples were not the cause of their cancers. *Nat'l Union Fire Ins. Co. of Pittsburgh PA v. SPX Flow US, LLC*, No. 18-80332, 2019

²⁵ (Godleski Newsome Rep. at 7.)

WL 1227987, at *4 (S.D. Fla. Mar. 14, 2019) (citation omitted). As a result, plaintiffs' argument that Drs. Felix and Longacre lack a valid methodology to "establish within a reasonable degree of medical certainty that Plaintiffs' tissue blocks were contaminated with talc and/or asbestos in the hospital pathology lab where they were diagnosed"²⁶ is irrelevant to the *Daubert* inquiry.

Second, there is also no merit to plaintiffs' argument that Drs. Felix and Longacre "offer no evidence . . . whatsoever, nor do they offer a single study or journal article, or reference of any kind" to support their opinions that the particles Dr. Godleski identified as consistent with talc and asbestos are unlikely to have been present in the plaintiffs' bodies such that they could have caused their various cancers.²⁷

As an initial matter, it is axiomatic that "[e]xperts need not specifically rely on texts in issuing opinions; they may rely on their own experience and expertise." *DeFronzo v. Conopco, Inc.*, No. 03-6777, 2005 WL 8177613, at *5 (N.D. Ill. June 30, 2005); *see also* Fed. R. Evid. 702 advisory committee's notes to 2000 amendment ("Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony."); *Equal*

²⁶ (Pls.' Br. at 8.)

²⁷ (*Id.* at 7.)

Emp. Opportunity Comm'n v. Mod. Grp., Ltd., No. 21-451, 2024 WL 1290450, at *9 (E.D. Tex. Mar. 25, 2024) (“For one matter, an expert may properly rely upon his own experience when offering an opinion.”); *Cantor v. Perelman*, No. 97-586, 2006 WL 3462596, at *7 (D. Del. Nov. 30, 2006) (“To the contrary, the Supreme Court has acknowledged that experts may base their testimony upon personal experience.”) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Drs. Felix and Longacre are two internationally recognized gynecologic pathologists with collectively almost 80 years of pathology experience, which they appropriately rely on to support their opinions regarding the appearance and reaction of live tissue to foreign particles.²⁸ In addition to relying on their own backgrounds and experiences in their work as pathologists, Drs. Felix and Longacre also cite scientific literature expressing the fundamental pathological principle that foreign agents, such as talc or asbestos, always cause a foreign body

²⁸ (See, e.g., Felix Dep. 192:20-193:10 (“Q. You make this recurring sentence in your reports . . . you say, ‘In the absence of an associated foreign body reaction, including the presence of foreign body giant cells and/or particle-laden macrophages, foreign materials in processed histology specimens is widely agreed by pathologists to be simple particulate contaminant introduced into the tissue at the time of surgical removal and/or tissue processing for histologic examination.’ When you say it’s widely agreed, what source are you relying on for that, or is that just your personal experience? A. Yes, it’s my . . . conversation with many -- many, many pathology colleagues.”).)

reaction in live tissue.²⁹ Thus, there is reliable scientific support for Drs. Felix and Longacre's opinions about tissue reaction, both in the form of their clinical experience and scientific citations.

Drs. Felix and Longacre also have reliable scientific evidence supporting their opinion that the particles Dr. Godleski purports to have found may have been the result of lab contamination. Based on their decades of experience as pathologists as well as scientific literature, Drs. Felix and Longacre describe in detail the ubiquitous nature of contamination in medical facilities, including pathology labs.³⁰ In addition, as explained above, Dr. Felix notes that it would be prohibitively expensive for labs to be designed to prevent particles of the size Dr. Godleski found from introduction into surgical tissue specimens and that, as a result, pathologists understand that the "vast majority of tissue slides will have microscopic particulate matter."³¹ Thus, "[i]n the absence of an associated foreign body reaction," "these particles are widely agreed by pathologists to be simple

²⁹ (Longacre *Newsome* Rep. at 11, 12, 14, 16 (citing Clement 2019, Reichert 2012; Perou 1973); Felix *Converse* Rep. at 9 (citing Shah 2017; Irving 2015; Reichert 2012; Ellis 1994; Hamilton 1984; de Brito 2017; Perou 1973); *see also* Felix Dep. 193:11-19.)

³⁰ (Felix *Converse* Rep. at 9, 10 (citing McDonald 2019; Perou 1973), 12; Felix Dep. 148:12-149:6.; Longacre *Newsome* Rep. at 12-15 (citing McDonald 2019).)

³¹ (Felix *Converse* Rep. at 9; *see also* Felix Dep. 192:20-193:19.)

particulate contaminants introduced to the tissue at the time of surgical removal and/or tissue processing for histologic examination.”³²

In addition, and as noted above, Dr. Godleski has himself admitted that there is a high potential for tissue contamination from the air, surfaces, and tools in hospitals and labs.³³ Indeed, Dr. Godleski conceded that even the surface of plaintiffs’ tissue samples may have been contaminated,³⁴ and that many, if not most, pathology slides will be contaminated with talc.³⁵ While Dr. Godleski claims to have controlled for the contamination, Drs. Felix and Longacre explain that these efforts were insufficient to reliably confirm that any particles identified were not the result of lab contamination, as detailed above.³⁶

For all of these reasons, there is ample support in the science and the record for the experts’ opinions that contamination is an alternative explanation for the

³² (Felix *Converse* Rep. at 9; *see also* Felix Dep. 192:20-193:19.)

³³ (*See, e.g.*, Godleski *Converse* Rep. at 4.)

³⁴ (3/28/24 Godleski Dep. 170:10-19 (“[W]e don’t analyze any particles that we find on the surface of the tissue because, even though it’s just the edge of the surface, it very -- has a definite chance of getting there by contamination in the laboratory. So we don’t analyze that.”).)

³⁵ (3/29/24 Godleski Dep. 91:12-92:2 (“But for many years, almost every pathology department just used boxes of 100 gloves that had a lot of particles on them and a lot of talc so that, if you sometimes look carefully at a block or a slide, you can see that contamination around the outside.”).)

³⁶ (*See, e.g.*, Felix *Converse* Rep. at 12.)

presence of particles allegedly consistent with talc/asbestos in the samples of the plaintiffs' tissue that Dr. Godleski reviewed.

II. PLAINTIFFS' QUALIFICATION ARGUMENTS ARE MERITLESS.

Plaintiffs also argue in their motion that neither expert is as qualified as Dr. Godleski to use certain highly specialized microscopy techniques.³⁷ To the extent plaintiffs intend to challenge Drs. Felix and Longacre's qualifications by so arguing, their criticisms have zero connection to the opinions they seek to exclude.

Dr. Godleski used specialized microscopy techniques (SEM and EDX) to identify the particles that he claims are consistent with talc and asbestos. While plaintiffs repeatedly note that Drs. Felix and Longacre did not use these same techniques (and allegedly are not qualified to do so),³⁸ such arguments are wholly irrelevant to their motion. Plaintiffs seek to exclude the testimony of Drs. Felix and Longacre to the extent they seek to opine that the particles observed by Dr. Godleski "are contaminants that somehow reached the internal structures of the tissue *after* the tissue was removed from Plaintiffs."³⁹ In other words, plaintiffs base their motion on Drs. Felix and Longacre's opinions as to where the particles

³⁷ (See, e.g., Pls.' Br. at 6 ("Drs. Felix and Longacre have no expertise whatsoever in particle identification by SEM or EDX.").)

³⁸ (See, e.g., *id.* at 3-4.)

³⁹ (*Id.* at 3.)

at issue originated, not on whether they exist, or the microscopy technology used to identify the particles. Notably, plaintiffs challenge neither Dr. Felix's nor Dr. Longacre's qualifications as pathologists—or their ability to reliably testify about foreign body reactions in live tissue or the potential sources of lab contamination—which is what enables them to offer the critiques of Dr. Godleski at issue. As a result, plaintiffs' assertions about Drs. Felix and Longacre's qualifications with respect to various microscopy tools are irrelevant and should be ignored.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court deny plaintiffs' motion to exclude the opinions of Drs. Felix and Longacre.

Dated: August 22, 2024

Respectfully submitted,

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